



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0341]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Federal-State Food Regulatory Program Standards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review--Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910-0760. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 240-994-7399, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Federal-State Food Regulatory Program Standards

This information collection supports the FDA's Animal Food (formerly Feed) Regulatory Program Standards (AFRPS) and Egg Regulatory Program Standards (ERPS). In the United States, Federal and State government agencies ensure the safety of human and animal food. FDA is responsible for ensuring that all human and animal food moving in interstate commerce, except those under the U.S. Department of Agriculture jurisdiction, are safe, wholesome, and labeled properly. States are responsible for conducting inspections and regulatory activities that help ensure human and animal food produced, processed, and distributed within their jurisdictions are safe and in compliance with State laws and regulations. States primarily perform inspections under their own regulatory authority. Some States conduct inspections of human and animal food facilities under contract with FDA. Because jurisdictions may overlap, FDA and States collaborate and share resources to protect human and animal food.

The FDA Food Safety Modernization Act calls for enhanced partnerships and provides a legal mandate for developing an Integrated Food Safety System (IFSS). FDA is committed to implementing an IFSS thereby optimizing coordination of human and animal food safety efforts with Federal, State, local, tribal, and territorial regulatory and public health agencies. Model standards provide a consistent, underlying foundation that is critical for uniformity across State and Federal agencies to ensure credibility of human and animal food programs within the IFSS. The AFRPS and ERPS provide a uniform and consistent approach to animal food and egg regulation in the United States. Implementation is voluntary.

The AFRPS and ERPS are the frameworks that each State should use to design, manage, and improve its animal food or egg regulatory program. Each standard has a purpose statement, requirement summary, description of program elements, projected outcomes, and a list of required documentation. When a state program voluntarily agrees to implement the standards, it must fully implement and maintain the individual program elements and documentation requirements in each standard in order to fully implement the standard. We invite you to visit

our website (<https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/national-integrated-food-safety-system-ifss-programs-and-initiatives/regulatory-program-standards#:~:text=Regulatory%20program%20standards%20establish%20a,regulating%20human%20and%20animal%20food>) for more information and to access the program standards.

Both the AFRPS and ERPS packages include forms, worksheets, and templates to help the State program assess and meet the program elements in the standard. State programs are not obligated to use the forms, worksheets, and templates. Other manual or automated forms, worksheets, and templates may be used as long as the pertinent data elements are present. States submit the information collected annually via email to the appropriate FDA program manager. Records and other documents specified in the AFRPS and ERPS must be maintained in good order by the state program and must be available to verify the implementation of each standard.

As set forth in the AFRPS and ERPS, the state program is expected to review and update its improvement plan on an annual basis. The state program completes an evaluation of its implementation status annually following the baseline evaluation by reviewing and updating the self-assessment worksheets and required documentation for each standard. The evaluation is needed to determine if each standard's requirements are, or remain, fully met, partially met, or not met. The State program revises the improvement plan based upon this evaluation.

In collaboration with the State Governments, FDA recently completed a revision of the animal food program standards that incorporated the most current knowledge and lessons learned in the application of the 2020 AFRPS by State partners and program assessment by FDA. In an effort to improve program effectiveness, understanding and clarity, changes to the AFRPS include those to program definitions, all 11 program standards, appendices, and assessment worksheets that may be used by the States who have adopted the AFRPS. Such changes include updates to terminology, most notably replacing the term "animal feed" with "animal food," consistent with the terminology of the FDA Food Safety Modernization Act, and minor editorial changes. Other changes include streamlining both the standards and appendices to be less

prescriptive in nature and focus more on capturing information needs. This process results in an overall reduction of 11 appendices (most of which provided more program specific guidance or examples and therefore are not expected to change the burden) and a reformatting of the remaining appendices to be more uniform, succinct, and tabular in structure. The revised program standards are the result of external collaboration and coordination between FDA, the Association of American Feed Control Officials and state governments in which we consider any formal comments received on the 2020 edition of the program standards.

Description of Respondents: Respondents are state departments of agriculture or health enrolled in the AFRPS or ERPS (State Governments).

In the *Federal Register* of November 3, 2022 (87 FR 66307), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received and considered three comments. Two comments questioned the value of transitioning from the term “animal feed” to “animal food,” expressing concern for potential confusion unless other entities including member states also changed their terminology. The term “food” is defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(f)) (the FD&C Act) as “articles used for food or drink for man or other animals.” Section 201(w) of the FD&C Act defines “animal feed” more specifically as, “an article which is intended for use for food for animals other than man and which is intended for use as a substantial source of nutrients in the diet of the animal, and is not limited to a mixture intended to be the sole ration of the animal.” We believe the term “animal feed” is a useful distinction in some circumstances, but that “food” or “animal food” more accurately describes the regulated market.

One comment addressed public access to government data and the Federal policy development process, among other topics, all of which we consider to be outside the scope of this information collection. Respondents to this information collection maintain records and provide procedures and other documentation to demonstrate a standardized animal feed regulatory program. Another comment questioned the practical utility of the AFRPS, suggesting

that FDA should implement “a program that encourages uniform enforcement of laws/regulations across all 50 States.” We believe the AFRPS is the best way to achieve that goal.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Type of Respondents; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
State, local, Territorial, and/or Tribal Governments; submission of data elements to FDA consistent with AFRPS	25	1	25	569	14,225
State, local, Territorial, and/or Tribal Governments; submission of data elements to FDA consistent with ERPS	2	1	2	569	1,138
Total					15,363

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2.--Estimated Annual Recordkeeping Burden¹

Type of Respondents; Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
State, local, Territorial, and/or Tribal Governments; records maintenance for data elements consistent with AFRPS	25	11	275	40	11,000
State, local, Territorial, and/or Tribal Governments; records maintenance for data elements consistent with ERPS	2	10	20	40	800
Total					11,800

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

No change in burden is expected to be incurred with the implementation of the revised AFRPS. However, based on a review of the information collection since our last submission, the estimated burden for the information collection reflects an overall adjustment increase of 188 responses and a corresponding increase of 2,817 burden hours. We adjusted the number of respondents to the information collection associated with the AFRPS to reflect a reduction in enrollment since our last evaluation. Also, since the publication of the 60-day notice, we adjusted the number of respondents to the information collection to reflect a reduction in ERPS enrollment. In addition, based on the Agency’s experience over the past 3 years, we added

reporting burden and adjusted the recordkeeping burden estimates associated with the AFRPS and ERPS, resulting in an increase in responses and burden hours.

Dated: April 24, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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